

Clarification on Acceptable Infant Formulas

PURPOSE:

To clarify acceptable infant formulas used in the Child Nutrition Programs.

SCOPE:

Sponsors of the Child and Adult Care Food Program, School Breakfast Program, and the National School Lunch Program.

DESCRIPTION:

**1. Must a formula served (in the CACFP) be listed exactly as it says on the Child and Adult Care Food Program approved list?**

The answer is a qualified no. The current list of the *Iron-Fortified Formulas That Do Not Require a Medical Statement* (Policy Instruction 98-02) is NOT an inclusive list, because new infant formula products are continually being developed.

According to the Child and Adult Care Food Program (CACFP) regulations, 7 CFR 226.20(b)(2), “either breast milk or iron-fortified infant formula, or portions of both, must be served for the entire first year.” Any product labeled as an iron-fortified infant formula, legally must meet the Food and Drug Administration (FDA)’s definition, 21 CFR 107.10(b)(4)(i), as a product, “which contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.” The number of milligrams of iron per 100 kilocalories of formula can be found on the nutrition label of infant formulas.

**2. Must a provider have a medical statement on file for an infant formula to be part of a reimbursable meal?**

If a formula is not on the current list of the *Iron-Fortified Formulas That Do Not Require a Medical Statement*, a child care provider or institution may use the following criteria to determine whether or not a formula is reimbursable under the CACFP without the need of a medical statement:

a. Ensure that the formula is not listed as an FDA Exempt Infant Formula. An exempt infant formula is an infant formula labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems (21 CFR 107.3). Formulas classified as Exempt Infant Formulas by FDA require a medical statement in order to be served to infants under the CACFP as part of a reimbursable meal. A medical statement must

be signed by a licensed physician if an infant is considered disabled according to USDA's regulation, or a recognized medical authority specified by the State Agency if an infant has a medical or other special dietary needs. To check whether or not an infant formula is an FDA Exempt Infant Formula, visit FDA's website at <http://www.cfsan.fda.gov/~dms/infexmp.html>.

b. Examine the nutrition label to make sure that the formula is iron-fortified. The statement "Infant Formula with Iron" or a similar statement must be on the label.

c. Be aware of the fact that all infant formulas marketed in the United States must meet the nutrient specifications listed in FDA Regulation, 21 CFR 107 (<http://www.cfsan.fda.gov/~lrd/cfr107.html#spD>) and in the Section 412 of the Food, Drug, and Cosmetic Act (<http://www.fda.gov/opacom/laws/fdcast/fdcact4.htm#sec412>). If a formula is purchased outside of the United States, it is likely that FDA does not regulate the formula; therefore, it may not be creditable under the CACFP.

The nutritive values of each formula are listed on the product's nutrition label. Infant formula manufacturers may have their own proprietary formulations, but they must contain at least the minimum levels of all nutrients specified in FDA regulations without going over the maximum levels, when maximum levels are specified.

d.) Also be aware of the fact that manufacturers of infant formula are required by FDA regulation to follow current Good Manufacturing Practices, including quality control procedures to assure that the infant formula provides nutrients in accordance with Section 412 of the Food, Drug, and Cosmetic Act, and to assure that the infant formula is manufactured in a manner designed to prevent adulteration.

A childcare provider can serve a formula if the exact product is on the current list of *Iron-Fortified Formulas* without the need of obtaining a medical statement.

In a recent memorandum to USDA, the issue of whether the two specific brands of infant formulas are creditable was questioned. Similac Advance is an iron-fortified infant formula that is currently included in the list of *Iron-Fortified Formulas That Do Not Require a Medical Statement*. Similac Alimentum Advanced is an infant formula that is on the FDA Exempt Infant Formula list; therefore, it is not creditable unless supported by a statement from a licensed physician or a recognized medical authority specified by the State Agency, as appropriate, that indicates the need for this special formula.

If a sponsor or an institution is not sure of whether or not an infant formula is creditable under the CACFP, they should contact the State Agency who can contact FNS for assistance, as needed.

**3. Can USDA provide guidance about a formula supplied by a parent that is not iron-fortified? Would service of this product require a medical statement in order to be creditable for a reimbursable meal for an infant?**

As stated above, according to 7 CFR 226.20(b)(2), “either breast milk or iron-fortified formula, or portions of both, must be served for the entire first year.” In addition, Page 24 of *Feeding Infants: A Guide for use in the Child Nutrition Programs*, Paragraph 2, states that low-iron formulas do not meet the meal pattern and may be served as a dietary substitution only if an infant is unable to consume iron-fortified infant formula because of medical or other special dietary needs. The substitution can only be made when supported by a statement from a licensed physician or a recognized medical authority that indicates the recommended infant formula. These rules apply to formula provided by the CACFP facility and to formula provided by the parent.

USDA responses to these questions pertain to meals served to infants in the CACFP, as well as, to meals containing infant formula under the National School Lunch Program or the School Breakfast Program.

Source: USDA, Food and Nutrition Policy Memorandum #05-07, Dated, December 2, 2004